

Applicants: Robert E. Canfield, et al.  
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#### REMARKS

Claim 4 is pending in this application. Claim 4 has been amended to more particularly point out what applicants regard as the invention. Support for this amendment can be found in the specification at, inter alia, page 10, lines 15-17. Applicants submit that this amendment raises no issue of new matter. Thus, claim 4 is now pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the May 7, 2003 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

#### Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 4 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner alleged that the specification lacks written support for an antibody which competitively inhibits the binding of the B505 antibody to hLHb core fragment.

In response to the rejection of claim 4, applicants respectfully traverse.

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Claim 4 is directed to an antibody which binds to the hLH $\beta$  core fragment (hLH $\beta$ cf) and competitively inhibits the binding of the B505 antibody thereto.

The burden is on the Examiner to show by a preponderance of the evidence why a person skilled in the art would not recognize in applicants' disclosure a description of the invention defined by the claims. M.P.E.P. §2163.04.

Applicants understand the Examiner's rejection to be based on a combination of three factors: (1) the alleged lack of a specific disclosure of an antibody which competitively inhibits the binding of the B505 antibody; (2) applicants' reliance on what one of skill in the art performing the immunoassays disclosed in the specification would necessarily arrive at; and (3) the breadth of the claim, which allegedly encompasses additional antibodies outside the disclosure of the competitive immunoassays of the specification.

(1) In response to the Examiner's assertion that the specification lacks a specific disclosure of an antibody which competitively inhibits the binding of the B505 antibody to hLH $\beta$ cf, applicants note that additional working examples are not required in order to demonstrate possession of the claimed invention.

Possession may be shown in a variety of ways including description of an actual reduction to practice,... or by describing distinguishing identifying characteristics sufficient to show

that applicant was in possession of the claimed invention.

M.P.E.P. §2163.02. (emphasis added). Applicants maintain that the elements of claim 4 are sufficient to identify and distinguish the claimed antibody. Specifically, claim 4 recites the binding characteristics of the antibody. Each antibody that satisfies claim 4 must both bind to hLHβcf and compete with B505 for binding to the same. Applicants point out that antibodies are routinely identified and defined based solely on their affinity and specificity for a particular antigen, this being sufficient to distinguish a given class of antibodies. Applicants maintain that the antibody of claim 4 will necessarily have an affinity and specificity for hLHβcf that is at least comparable to that of B505. Applicants maintain that the Examiner has not demonstrated otherwise nor indicated what more would be required to describe the claimed antibody.

(2) In response to the Examiner's assertion that applicants rely on what one of skill in the art would necessarily arrive at, applicants maintain that it is not a mere probability or possibility, but a certainty, that one of skill could obtain the antibodies of claim 4 by using the teachings of the instant disclosure in combination with methods routine in the art.

In support of this position, applicants note the high level of skill in the art of monoclonal antibody technology. In *In Re Wands*, 858 F.2d 731 (Fed. Cir. 1998), the court addressed the issue of whether a monoclonal antibody-based method claim satisfied the requirements of 35 U.S.C. §112, first paragraph.

Regarding the patent addressed in Wands, only a single deposited hybridoma was disclosed which produced an antibody which could be used in the claimed method. Although the specific issue adjudicated was one of enablement and not written description, the court recognized that the level of skill was high enough to enable a practitioner in the art to make and use monoclonal antibodies having a particular binding affinity to the antigen in question, without requiring further working examples. In short, the Wands court concluded that the antibody-based claims adjudicated - which parallel the instant claims - satisfied the requirements of §112, first paragraph.

(3) In response to the Examiner's assertion regarding the breadth of claim 4, but without conceding the correctness thereof, applicants note that claim 4 excludes anti-idiotypic antibodies. Applicants maintain that claim 4, as amended, encompasses only antibodies supported by the disclosure of the instant specification, namely antibodies which both bind to the hLH $\beta$  core fragment and competitively inhibit the binding of the B505 antibody thereto.

In summary, applicants maintain that the high level of skill in the art of monoclonal antibody technology and screening, coupled with the teachings of competitive binding assays using radiolabeled hLH $\beta$  core fragment in the instant specification (see for example, page 17, line 18 through page 19, line 25) clearly demonstrate that applicants were in possession of the claimed invention.

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In view of the teachings of the instant specification, applicants maintain that claim 4 satisfies the written description requirement of 35 U.S.C. §112, first paragraph.

### Summary

In view of the remarks made herein, applicants maintain that the claim pending in this application is in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
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